510(k) Summary

APR 1 8 2013

Submission Date:	March 1, 2013
Submitter Information:	Alphatec Spine 5818 El Camino Real Carlsbad, CA 92008 Ph# (760) 431-9286 Fax# (760) 431-0289
Contact:	Nadine Smith Senior Regulatory Affairs Specialist Ph# (760) 494-6717
Trade/Model Name:	Epicage Interbody Fusion System
Common Name:	Orthosis, Intervertebral Body Fusion Device
Classification Regulation:	21 CFR 888.3080 Class II
Product Code(s):	MAX

Device Description:

The Epicage System implants are manufactured from implant grade PEEK with a surgical grade titanium alloy pin and 2 tantalum beads to facilitate visualization. The delivery system contains portals in sizes to match the implants sizes and general surgical instruments to assist in preparation and device delivery. The portals are integral to the system and are considered an accessory (Class II) all other instruments are Class I. The system can be used with a mid-line portal for a modified TLIF procedure or an oblique portal for a traditional TLIF approach. The implants of the system are available non-sterile and gamma sterilized.

Indications for Use:

The Epicage Interbody Fusion Device is intended for interbody fusion procedures and is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone. Patients should have received six months of non-operative treatment prior to treatment with the devices. The device is intended to be used with supplemental posterior fixation approved for use in the lumbar spine such as Alphatec Spine's Zodiac Polyaxial Spinal Fixation System and/or Illico Posterior Fixation System.

Substantial Equivalence Claimed:

The subject Epicage Interbody Fusion System is substantially equivalent to the predicate Epicage Interbody Fusion System (K092901) with the same intended use and technological characteristics. The subject system is manufactured from the same materials and manufacturing processes with equivalent performance, labeling, biocompatibility, and standards.

Technical Characteristics

The implants of the Epicage System are available in sizes 25mm and 30mm with multiple heights (8mm, 10mm, 12mm 14mm) manufactured from polyetheretherketone (PEEK Optima LT1 conforming to ASTM F-2026), surgical grade titanium alloy (TI-6Al-4V ELI conforming to ASTM F-136) with radiographic markers made from tantalum (conforming to ASTM F-560). Implants are available both non-sterile and sterile. The delivery system portals are manufactured from stainless steel in sizes to match the implants. The midline portal supports a modified TLIF procedure and the oblique portals are designed for a traditional TLIF approach. The portals and instruments are provided non-sterile with validated cleaning and sterilization parameters.

Non-Clinical Performance Testing

The following testing was conducted to support substantial equivalence to the predicate device.

Sterilization testing:

- Gamma Sterilization Validation
- Sterile Package Performance Validation

Performance testing:

- Static Axial Compression, Torsion, and Shear per ASTM F2077
- Dynamic Axial Compression, Torsion, and Shear per ASTM F2077
- Subsidence per ASTM 2267
- Expulsion per ASTM Draft F04.25.0202
- Epicage Portal Evaluation
- User Validation – Cadaver Lab

All testing passed the acceptance criteria and the results were substantially equivalent to the predicate device.

Conclusion

The Epicage Interbody Fusion System, demonstrated to be substantial equivalent to the Predicate Epicage System, is based on design, materials, intended use, and performance to the predicate systems identified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

April 18, 2013

Alphatec Spine, Incorporated
% Ms. Nadine Smith
Senior Regulatory Affairs Specialist
5818 El Camino Real
Carlsbad, California 92008

Re: K130548
Trade/Device Name: Epicage Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: March 14, 2013
Received: March 19, 2013

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130548

Device Name: Epicage Interbody Fusion System

Indications For Use:

The Epicage Interbody Fusion Device is intended for interbody fusion procedures and is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone. Patients should have received six months of non-operative treatment prior to treatment with the devices. The device is intended to be used with supplemental posterior fixation approved for use in the lumbar spine such as Alphatec Spine's Zodiac Polyaxial Spinal Fixation System and/or Illico Posterior Fixation System.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices